DETECTION OF DIASTOLIC HEART FAILURE

Technical Field

The present invention relates to an implantable medical apparatus for
5   detecting diastolic heart failure, DHF, comprising a DHF determining device for
determining at least one DHF parameter for detecting a DHF state of the heart of a
patient. The invention also relates to a pacemaker having such an apparatus, and a
method for detecting diastolic heart failure, DHF, comprising the step of determining
at least one DHF parameter for detecting a DHF state.

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Background

There is a growing recognition that congestive heart failure caused by a
predominant abnormality in the diastolic function, i.e. diastolic heart failure, DHF, is
both common and causes significant morbidity and mortality. Therefore early
15   detection of DHF is important such that a suitable treatment can be started. Patients
do not, however, seem to have symptoms at an early stage. In addition it has been
hard to separate diastolic and systolic heart failure and they may also exist
simultaneously.

The time progress of different phases of diastole of a patient suffering from
20   DHF is changed vis-à-vis that of a healthy person, see Michael R. Zile and Dirk L.
Brusaert, "New Concepts in Diastolic Dysfunction and Diastolic Heart Failure: Part
I", Circulation 2002; 105: 1387. Thus DHF can be divided into three phases, see
figure 1. Figure 1a shows left atrial pressure, LA dotted line, and left ventricular
pressure, LV solid line, as functions of time for a normal, healthy state and for three
25   phases of DHF. The first phase of DHF is referred to as "Impaired Relaxation". In
this phase characteristic times related to relaxation and filling of the left ventricle is
prolonged compared to corresponding times of a normal heart. After this phase the
disease progresses into a phase called "Pseudonormal". In this phase the heart
compensates and the characteristic times returns to more normal values, close to
30   those of the normal heart. This phase is followed by the final phase of DHF called
"Restrictive". In the final phase the characteristic times are shorter than for the
normal heart. Figure 1b shows corresponding measured mitral blood flow velocities.
Letter "E" denotes the so-called E-wave, early filling of the ventricle, and "A" the A-
wave, contribution from the atrium during its contraction.

The purpose of the present invention is to utilize these changes in time during diastole of patients suffering from DHF for proposing a technique for DHF detection.

Disclosure of the Invention

5   This purpose is obtained by an apparatus, a pacemaker and a method of the kind mentioned in the introductory portion of the description and having the characterizing features of claims 1, 17 and 18 respectively.

Thus with the present invention early detection of DHF is possible and it is also possible to detect how the disease progresses. Even the beginning of a DHF of

10   a healthy person can be detected.

According to advantageous embodiments of the apparatus according to the invention the DHF determining device comprises sensor and calculating means for determining the time, DT, from the occurrence of peak blood flow velocity through the mitral valve to zero blood flow velocity therethrough as said DHF parameter.The

15   sensor and calculating means are adapted to determine DT by extrapolating the mitral blood flow velocity to zero, if zero velocity is not obtained before atrial contraction. The sensor and calculating means are then preferably adapted to determine the time derivative of the blood flow velocity through the mitral valve shortly after said peak blood flow velocity for use for linearly extrapolating the blood

20   flow velocity to zero. DT denotes the E-wave deceleration time or "Dec time" related to the early filling of the left ventricle as mentioned above. If zero velocity is not obtained due to the atrial contraction, so-called A-wave influence, which will be described more in detail below. DT can consequently be determined by extrapolation in such situations.

25   According to still another advantageous embodiment of the apparatus according to the invention the DHF determining device comprises sensor and calculating means for determining isovolumic relaxation time, IVRT, i.e. the time from the closing of the aortic valve to the opening of the mitralis valve, as said DHF parameter.

30   According to yet other advantageous embodiments of the apparatus according to the invention the sensor and calculating means comprise a means for measuring IEGM or a means for measuring an impedance in the patient 's heart or a sound sensor or an accelerometer, intended to be placed on the left ventricle of the patient 's heart, for determining DT and/or IVRT. Thus e.g. IVRT can be

determined from impedance measurements between the left and right ventricles, or possibly between the left ventricle and right atrium. Since there is no change in the blood volume between electrodes located as indicated above during IVRT the impedance will be substantially constant. IVRT can consequently be identified as a "still" period in the impedance after systole. IVRT can also be determined by an accelerometer positioned on the left ventricle, for instance in one of the coronary veins running on the outside of the left ventricle. IVRT is then determined by the time the ventricle is still after systole, since the ventricle is still during IVRT. No blood enters or leaves the ventricle during this phase of the cardiac cycle, only a redistribution of the pressure takes place within the ventricle without change of volume of the ventricle. DT can be determined by e.g. listening to the blood flow through the mitralis valve. The blood velocity is correlated to the frequency of the heart sound signal, its derivative corresponds to the acceleration of the blood, and DT is calculated therefrom.

        According to other advantageous embodiments of the apparatus according to the invention the DHF determining device is adapted to determine the time length at predetermined time intervals and a storing means is provided for storing said determined time lengths. The DHF determining device can alternatively be adapted to determine changes in said time length and a storing means be provided for storing the determined changes in time length. During the follow-up of the patient stored parameters are downloaded from the storing means and evaluated by the physician for studying the progression of the disease It is also possible to provide an alerting means to be triggered if deviations of the determined time length from predetermined limit values exceed a predetermined threshold value, or a change in the determined time length exceeds a predetermined threshold value. Thus in response to the detection of a change in the DHF parameter indicating that the patient is developing DHF or the patient is progressing into a new phase of DHF an alert can be sent calling for a follow-up by a physician.

        The invention also relates to a pacemaker provided with the apparatus for detecting DHF and control means for optimising pacing therapy and pacemaker settings depending on the determined time length, as well as a method of detecting DHF.

Brief Description of the Drawings

To explain the invention in greater detail embodiments of the invention will now be described with reference to the drawings on which figure1a and b shows left ventricular and left atrial pressures and mitral blood flow velocity respectively for a

5   normal heart and for three phases of DHF, figures 2 – 4 illustrate impedance measurements for determining IVRT in three embodiments of the invention, figure 5 illustrates an embodiment of the invention comprising special sensors for DT and IVRT determination, and figure 6 is a diagram illustrating when DT and IVRT values are stored for later evaluation and when a DHF alert is sent according to an

10   exemplifying embodiment of the invention.

Description of Preferred Embodiments

Figure 1a shows left ventricular pressure, LV Press solid line, and left atrial pressure, LA Press dotted line, during diastole and figure 1b corresponding mitral

15   Doppler left ventricular blood inflow, as measured by echocardiography, for a normal healthy heart and for three phases of diastole. Normal diastolic function is characterized by a predominant early diastolic mitral flow, E-wave, exceeding the velocity of left ventricular filling contributed by atrial contraction, A-wave in the figure. With impaired relaxation atrial contraction contributes relatively more to

20   ventricular filling, viz. A-wave > E-wave, with prolonged deceleration of the E-wave, usually > 240 msec. This phase of DHF "Impaired Relaxation" is common with increasing age and may identify patients at risk for DHF. When ventricular diastolic pressure increases to the point where atrial contraction contributes little to the filling, the E-wave again becomes predominant but with rapid deceleration, first in a

25   "Pseudonormal" pattern and ultimately in a "Restrictive" pattern, characterized by a high E-wave velocity of usually more than twice the A-wave velocity.

One of the time lengths which can be used to indicate the progress of DHF is the E-wave deceleration time, DT "Dec. Time", see figure 1b. DT is defined as the time length from the point of blood peak velocity through the mitral valve to the point

30   of zero velocity, cf. figure 1b. If zero velocity is not reached due to the A-wave influence, DT is calculated by extrapolation as illustrated in figure 1b for the phase "Impaired Relaxation". The time derivative of the flow velocity through the mitral valve shortly after the blood flow peak velocity is determined for use for linearly

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extrapolating the blood flow velocity to zero. By measuring DT the beginning of a
DHF and its progress can be detected.

The progress of DHF can be divided into three phases as mentioned above
and each of these phases causes a change in DT, see figure 1b. The first phase of
5   DHF is referred to as "Impaired Relaxation". During this phase DT is much longer
than in a normal heart. After this phase the disease progresses into a phase called
"Pseudonormal". In this phase the heart compensates and DT returns to more
normal values, close to the DT value of a normal heart. This phase is followed by
the final stage of DHF called "Restrictive" In this phase DT is shorter than DT of a
10   normal healthy heart.

Another time length which can be used to indicate the progress of DHF is
the isovolumic relaxation time, IVRT, as mentioned above. In the "Impaired
Relaxation" phase of diastole IVRT is longer than for a healthy heart, as appears
from figure 1b. In the "Pseudonormal" phase the heart is compensating and IVRT
15   returns to more normal values. In the final "Restrictive" phase IVRT is decreased to
a shorter value than IVRT of the normal heart, cf. figure 1b.

A pacemaker according to the invention will preferably use its sensors for
determining IEGMs or impedance measurements for measuring and calculating DT
or IVRT at given time intervals, as will be described in further details below, and
20   either store DT or IVRT or changes in DT or IVRT in the memory of the pacemaker.
In the follow-up the development of DT or IVRT over time is downloaded from the
pacemaker and the physician can evaluate the results and study the progression or
regression of the disease.

An alerting means can also be provided to send an alert, calling for a follow-
25   up for the patient in question, in response to the detection of a change in DT or
IVRT indicating that the patient is developing DHF or the patient is progressing into
a new phase of DHF.

IVRT is initiated by the closing of the aortic valve and terminated by the
opening of the mitral valve. To determine when the aortic and mitral valves closes
30   and opens respectively impedance measurements or some kind of sensor can be
used. Figure 2 illustrates an example of impedance measurements between left and
right ventricles 1, 3. A current is supplied between the pacemaker case,
schematically shown at 2, and the tip electrode 4 of a right ventricular lead 6, and

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the resulting voltage is measured between the ring electrode 8 of the ventricular lead 6 and the tip electrode 10 of a unipolar coronary sinus lead 12.

Figure 3 illustrates an example wherein current is fed between the ring electrode 14 of a bipolar right atrial lead 16 and the ring electrode 20 of a bipolar coronary sinus lead 18, and the resulting voltage is measured between the tip electrodes 22 and 24 of the right atrial lead 16 and the coronary sinus lead 18 respectively.

Figure 4 illustrates still another embodiment wherein current is supplied between the tip electrode 26 of a bipolar right ventricular lead 28 and the ring electrode 30 of a bipolar coronary sinus lead 32, and the resulting voltage is measured between the ring electrode 34 of the right ventricular lead 28 and the tip electrode 36 of the coronary sinus lead 32.

Since there is practically no change in the blood volume during IVRT between the electrodes used in the embodiments illustrated above, the impedance measured in this way is substantially constant. IVRT can consequently be identified as the "still" period in the impedance after systole.

Figure 5 illustrates an embodiment wherein a special sensor 38 is used. This sensor can be of a kind which picks up noise or registers mechanical events, such as for instance a so-called CMES-sensor, cardiac mechanical sensor,. The CMES-sensor is a piezoelectric sensor the output signal of which contains a. o. pressure information. This information comprises several components, and in a certain frequency range the sensor is sensible to noise, i.e. it works as a microphone. The signal from the sensor comprises also the true pressure and its derivative. By suitable filtering of the sensor signal valve openings and closings can be detected.

The sensor 38 in figure 5 can alternatively comprise an accelerometer positioned on the left ventricle, for instance in one of the coronary veins running on the outside of the left ventricle, as shown in the figure. IVRT is then detected as the time when the ventricle is still after systole. During this time no blood leaves or enters the ventricle which consequently does not change volume.

DT can be determined in an analogous way by impedance measurements or by noise measurements with the aid of a microphone positioned in a coronary vein as illustrated in figure 5, or positioned in the right ventricular apex. DT can also

be determined by an accelerometer positioned on the outside of the left side of the heart, i.e. in the coronary sinus.

The time length used as parameter for detection of DHF can also be determined by more than one of the above described techniques.

5   Typical values of IVRT of a healthy person are 70 – 90 msec depending on age and other parameters, and typical values of DT of a healthy person are 160 – 240 msec. IVRT and DT values above 90 and 240 msec respectively are assumed to characterize a state of impaired relaxation, and values below 70 and 160 msec respectively are characterizing the restrictive phase of DHF. Thus an increase or

10   decrease of IVRT and DT above or below the above mentioned limit values are indications of DHF and should therefore call for attention. This is illustrated in figure 6 which shows that time length values within the normal range are not stored, whereas time length values above or below the prescribed limit values are stored together with their times of occurrence. These measured time length values outside

15   the normal range can also be triggering an alert.

The amount of deviation of the measured time lengths above or below their rspective limit values is an indication of the severity of the DHF.

Thus, if the IVRT and DT values fall outside their respective normal ranges these values are stored together with the amounts by which the time lengths exceed

20   or are below the respective limit. Possible erroneous measurement values are filtered out, such that single or very few time length values outside the normal ranges should not result in a DHF detection, and not trigger a possible alert.

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